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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,569	06/14/2001	Pushpa Khanna	U 013488-3	5858

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,569

Applicant(s)

KHANNA, PUSHPA

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The restriction requirement made September 10, 2002 in Paper No. 10 is withdrawn.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, drawn to a protein and a process for the extraction of a protein, classified in class 530, subclass 300.
 - II. Claim 2-4, drawn to a method of protein extraction, classified in class 514, subclass 2.
 - III. Claim 5, drawn to a method of treating diabetes, classified in class 514, subclass 2.
 - IV. Claim 6, drawn to a method of making a hypoglycemic composition, classified in class 514, subclass 2.

Invention I is related to the inventions of II-IV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein of invention I can be used in a materially different process such as generating antibodies or in each of the methods of invention II through IV, for example.

The methods of inventions II through IV require different products and steps and have different endpoints. Therefore, inventions II and III are patentably distinct.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with John Richards on November 26, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claim 1. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2-6 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

4. The Draftsman has approved drawing sheets 1-18 submitted on June 14, 2001.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in India (560/DEL/99 and 561/DEL/99) on April 13, 1999. It is noted, however, that applicant has not filed a certified copy of the 560/DEL/99 and 561/DEL/99 application as required by 35 U.S.C. 119(b).

This application repeats a substantial portion of prior Application No. PCT/IN99/00052, filed September 28, 1999, and adds and claims additional disclosure not presented in the prior application. Priority to PCT/IN99/00052 filed on 09/28/1999 is not granted as the table in claim

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1 of the instant application is not supported in the priority document. The priority date of the instant application is June 14, 2001.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on April 10, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

7. Claim 1 is objected to because of the following informalities:

Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations (MPEP §608.01(m)). See *Fressola v. Man-beck*, 36 USPQ2d 1211 (D.D.C. 1995). Additionally, the characteristics listed under I(vii) are grammatically inconsistent with the preamble of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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9. The table used in claim 1 does not clearly define protein the for the following reasons:
 - a. The recitation of amounts and percents (i.e, aaa936 avg nmoles, ugrams, mole percent, and # resiuiues) in the table headings are not clear. Are these table headings to be interpreted as limiting the amino acids to specific amounts or does the claim encompass the recited amino acids in unspecified amounts?
 - b. The use of "pro+cys" is unclear because the amount of each is not specified and could essentially be interpreted as only "pro" or "cys".
 - c. The meaning of the parentheses used in the table is unclear.
 - d. It is unclear why some amino acids are capitalized and others not.
 - e. The claim is indefinite for the use of % injected.
 - f. It is not clear what data in the table should literally be used as a claim limitation and what is not relevant.
 - g. The terms 'Cysac', 'cmcys', 'Asx', and 'ileu' are not defined and are thus indefinite. Amino acids are to be reference as listed in WIPO Standard ST.25 (1998), Appendix 2, Table 3.
 - h. Does the protein contain "trp"?
 - i. Does the protein contain 160 residues or is this the sample size?
10. Claim 1 recites a polypeptide "comprising amino acids including". The use of "including" together with comprising renders the claim indefinite because it connotes that the polypeptide comprises amino scids other than those listed.
11. The term "novel" in claim 1 is a relative term which renders the claim indefinite. The term "novel" is not defined by the claim, the specification does not provide a standard for

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ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

12. The term "partially" in claim 1(i) is a relative term which renders the claim indefinite. The term "partially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

13. Note also that "capable of" does not equate to must invariably occur; and, thus the claims are indefinite as indicating only a potential function/action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jeevathayaparan *et al.* (Journal of the National Science Council of Sri Lanka, (1991) Vol. 19, No.1, pp. 19-24).

Jeevathayaparan *et al.* teach extracts and commercially available capsules made from *Momordica charantia*, which have hypoglycemic activity when administered orally. The extract taught by Jeevathayaparan *et al.* would comprise the protein of claim 1. Even though Jeevathayaparan *et al.* does not teach the properties of the protein as those defined in claim 1, absent factual evidence to the contrary these properties are inherent to the protein found in the extract of *Momordica charantia* taught by Jeevathayaparan *et al.*.

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It is noted that in *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes properties and functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). Thus, the reference anticipates the claimed invention.

Advisory Information

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
December 16, 2002

SKS

Brenda Brumback
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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600